

110TH CONGRESS  
1ST SESSION

# S. 2466

To amend the Public Health Service Act to increase the availability of vaccines, and for other purposes.

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IN THE SENATE OF THE UNITED STATES

DECEMBER 13, 2007

Mr. KENNEDY introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To amend the Public Health Service Act to increase the availability of vaccines, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Vaccines for the Unin-  
5       sured Adult Act of 2008”.

6       **SEC. 2. CERTAIN AUTHORITIES REGARDING ADULT IMMUNIZATIONS.**  
7

8       (a) IN GENERAL.—Part B of title III of the Public  
9       Health Service Act (42 U.S.C. 243 et seq.) is amended—

1 (1) by redesignating section 317A as section  
2 317A–1; and

3 (2) by inserting after section 317 the following  
4 section:

5 **“SEC. 317A. CERTAIN AUTHORITIES REGARDING ADULT IM-**  
6 **MUNIZATIONS.**

7 “(a) IMMUNIZATION PROGRAM FOR ELIGIBLE  
8 ADULTS.—

9 “(1) IN GENERAL.—The Secretary shall by reg-  
10 ulation establish a program for the distribution of  
11 qualified adult vaccines through States with ap-  
12 proved applications under paragraph (4)(C) and the  
13 payment of a fee for the administration of such vac-  
14 cines, under which program—

15 “(A) each vaccine-eligible adult, in receiv-  
16 ing an immunization with a qualified adult vac-  
17 cine from a program-registered provider on or  
18 after October 1, 2009, is entitled to receive the  
19 immunization without charge for the cost of  
20 such vaccine; and

21 “(B)(i) each program-registered provider  
22 who administers such a vaccine to a vaccine-eli-  
23 gible adult on or after such date is entitled to  
24 receive such vaccine under the program without  
25 charge either for the vaccine or its delivery to

1 the provider and is entitled to receive payment  
2 for the administration of such vaccine; and

3 “(ii) no vaccine is distributed under the  
4 program to a provider, and no payment is made  
5 for the administration of the vaccine by such a  
6 provider, unless the provider is a program-reg-  
7 istered provider.

8 “(2) RELATIONSHIP TO PROGRAM FOR DIS-  
9 TRIBUTION OF PEDIATRIC VACCINES.—The provi-  
10 sions of the program under section 1928 of the So-  
11 cial Security Act (including provisions taking effect  
12 on or after the effective date of this section, other  
13 than subsection (f) of such section 1928) apply with  
14 respect to immunizations for vaccine-eligible adults  
15 under the program under paragraph (1) to the same  
16 extent and in the same manner as such provisions  
17 apply with respect to immunizations for vaccine-eli-  
18 gible children under the program under such section  
19 1928, except to the extent that such a provision con-  
20 flicts with this subsection. The preceding sentence  
21 may not be construed as having any effect on the  
22 program under title XIX of the Social Security Act,  
23 or as having the effect that, in the program under  
24 paragraph (1), State plans comparable to State  
25 plans under section 1902 of such Act are required.

1 “(3) VACCINE-ELIGIBLE ADULT.—

2 “(A) IN GENERAL.—For purposes of this  
3 subsection, the term ‘vaccine-eligible adult’  
4 means a federally vaccine-eligible adult or a  
5 State vaccine-eligible adult.

6 “(B) FEDERALLY VACCINE-ELIGIBLE  
7 ADULT.—For purposes of this subsection, the  
8 term ‘federally vaccine-eligible adult’ means any  
9 of the following:

10 “(i) An adult who is not insured.

11 “(ii) An adult who—

12 “(I) is administered a qualified  
13 adult vaccine by a Federally-qualified  
14 health center (as defined in section  
15 1905(l)(2)(B) of the Social Security  
16 Act), by any other entity that is a cov-  
17 ered entity under section 340B(a)(4),  
18 or by any public clinic; and

19 “(II) is not insured with respect  
20 to the vaccine.

21 “(iii) An adult who—

22 “(I) is administered a qualified  
23 adult vaccine while incarcerated in a  
24 Federal, State, or local penal or cor-  
25 rectional institution, including an

adult who is held pending judicial or  
administrative proceedings; and

“(II) is not insured with respect  
to the vaccine.

“(C) STATE VACCINE-ELIGIBLE ADULT.—

For purposes of this subsection, the term ‘State  
vaccine-eligible adult’ means, with respect to a  
State and a qualified adult vaccine, an adult  
who is within a class of adults for which the  
State is purchasing the vaccine pursuant to  
provisions that apply pursuant to paragraph  
(2).

“(4) PARTICIPATION OF STATES.—

“(A) IN GENERAL.—In the case of each  
State with an approved application under sub-  
paragraph (C), the Secretary shall provide, in  
accordance with provisions that apply pursuant  
to paragraph (2), for the purchase and delivery  
on behalf of the State, without charge to the  
State, of such quantities of qualified adult vac-  
cines as may be necessary for the administra-  
tion of such vaccines to all vaccine-eligible  
adults in the State on or after October 1, 2009.

“(B) PROGRAM CRITERIA.—The Secretary,  
in accordance with provisions that apply pursu-

ant to paragraph (2), shall establish criteria for  
State programs under paragraph (1).

“(C) STATE APPLICATION.—A State may  
participate in the program under paragraph (1)  
only if the State submits to the Secretary an  
application for such participation. The Sec-  
retary shall approve any such application  
that—

“(i) is submitted in such form and  
such manner as the Secretary may require;  
and

“(ii) demonstrates that the State is in  
compliance with criteria under subpara-  
graph (B) and the requirement of subpara-  
graph (D).

“(D) REQUIREMENT OF STATE MAINTENANCE OF IMMUNIZATION LAWS.—In the case  
of a State that had in effect as of July 1, 2008,  
a law that requires some or all health insurance  
policies or plans to provide some coverage with  
respect to an adult vaccine, the Secretary may  
not approve the State’s application under sub-  
paragraph (C) unless the State certifies to the  
Secretary that the State has not modified or re-

1           pealed such law in a manner that reduces the  
2           amount of coverage so required.

3           “(5) ADDITIONAL DEFINITIONS.—For purposes  
4           of this subsection:

5                   “(A) The term ‘adult’ means an individual  
6                   who is not a child as defined in section 1928 of  
7                   the Social Security Act.

8                   “(B) The term ‘adult vaccine’ means a fed-  
9                   erally recommended vaccine for adults.

10                   “(C)(i) The term ‘insured’, with respect to  
11                   an adult, means that the adult is enrolled  
12                   under, and entitled to benefits under, a health  
13                   insurance policy or plan, including a group  
14                   health plan, a prepaid health plan, or an em-  
15                   ployee welfare benefit plan under the Employee  
16                   Retirement Income Security Act of 1974.

17                   “(ii) An adult is not insured with respect  
18                   to a qualified adult vaccine if the adult is enti-  
19                   tled to benefits under such a health insurance  
20                   policy or plan, but such benefits are not avail-  
21                   able with respect to the cost of such vaccine.

22                   “(D) The term ‘qualified adult vaccine’  
23                   means an adult vaccine with respect to which a  
24                   contract is in effect pursuant to provisions that  
25                   apply pursuant to paragraph (2).

1           “(6) PAYMENT FOR VACCINE ADMINISTRA-  
2           TION.—

3                   “(A) IN GENERAL.—The amount of pay-  
4           ment for vaccine administration under the pro-  
5           gram under this section shall be the same as  
6           the amount established under the physician fee  
7           schedule under section 1848 of the Social Secu-  
8           rity Act for payment for administration of a  
9           vaccine under part B of title XVIII of such Act.

10                   “(B) ADMINISTRATIVE CONTRACTS.—The  
11           Secretary shall enter into such contracts or  
12           agreements with qualified carriers or inter-  
13           mediaries as may be necessary for the proc-  
14           essing of claims for payment for vaccine admin-  
15           istration under this section.

16                   “(7) DIRECT SPENDING.—The requirement  
17           under paragraph (1) that the Secretary carry out a  
18           program constitutes budget authority in advance of  
19           appropriations Acts, and represents the obligation of  
20           the Federal Government to make outlays to provide  
21           for immunizations of vaccine-eligible adults in ac-  
22           cordance with this subsection, including with respect  
23           to program-registered providers and with respect to  
24           the purchase and delivery of qualified adult vaccines



1 on behalf of States and with respect to the payment  
2 for vaccine administration.

3 “(b) EMERGENCY RESPONSE PLAN REGARDING  
4 SHORTAGES.—

5 “(1) DEVELOPMENT OF PLAN.—The Secretary  
6 shall develop and maintain a plan for the response  
7 of the Secretary to potential shortages in supplies of  
8 vaccines that would constitute public health emer-  
9 gencies. The plan shall include provisions with re-  
10 spect to—

11 “(A) communication among the relevant  
12 entities;

13 “(B) distribution of available supplies of  
14 the vaccine involved;

15 “(C) the designation of populations to be  
16 given priority for immunizations;

17 “(D) interactions with State and local gov-  
18 ernments;

19 “(E) the use of the vaccine stockpile; and

20 “(F) special considerations for specific vac-  
21 cines.

22 “(2) COMPLETION OF PLAN.—The initial plan  
23 under paragraph (1) shall be completed not later  
24 than 12 months after the date of the enactment of  
25 the Vaccines for the Uninsured Act of 2008.

1           “(3) STUDY ON REALLOCATION OF VACCINE.—

2           Not later than 1 year after the date of the enact-  
 3           ment of the Vaccines for the Uninsured Act of 2008,  
 4           the Secretary shall complete a study and submit a  
 5           report to the Congress on successful models and al-  
 6           ternatives for tracking and facilitating, in consulta-  
 7           tion with State and local health officials, reallocation  
 8           of vaccine at the local level in times of shortage or  
 9           emergency.

10          “(c) EDUCATION PROGRAM REGARDING ADULT IM-  
 11       MUNIZATIONS.—

12           “(1) IN GENERAL.—The Secretary shall develop  
 13           and implement a program to promote, among the  
 14           adult population, immunizations with federally rec-  
 15           ommended vaccines.

16           “(2) CONTENT OF PROGRAM.—The program  
 17           developed under paragraph (1) shall include the use  
 18           of a mass media campaign.

19           “(3) AUTHORIZATION OF APPROPRIATIONS.—  
 20           For the purpose of carrying out this subsection,  
 21           there are authorized to be appropriated such sums  
 22           as may be necessary for each of the fiscal years  
 23           2009 through 2013.

24          “(d) GENERAL DEFINITIONS.—For purposes of this  
 25       section:

1           “(1) The term ‘approved vaccine’ means a vac-  
 2           cine for which a biologics license under section 351  
 3           is in effect.

4           “(2) The term ‘federally recommended vaccine’,  
 5           with respect to an adult, means an approved vaccine  
 6           that—

7                   “(A) is recommended by the Advisory  
 8           Committee on Immunization Practices (an advi-  
 9           sory committee established by the Secretary,  
 10          acting through the Director of the Centers for  
 11          Disease Control and Prevention) with respect to  
 12          adults generally; or

13                   “(B) is recommended by such Advisory  
 14          Committee with respect to any group of adults  
 15          because of their health condition, their employ-  
 16          ment status, or any other factor.”.

17          (b) APPLICATION OF PEDIATRIC VACCINE MAINTENANCE OF EFFORT PROVISIONS TO ADULT VACCINES.—

18           (1) UNDER ERISA.—

19                   (A) IN GENERAL.—Section 609(d) of Em-  
 20          ployee Retirement Income Security Act of 1974  
 21          (29 U.S.C. 1169(d)) is amended—  
 22                   (i) in the heading, by inserting “OR

23                   ADULT” after “PEDIATRIC”; and  
 24

1 (ii) by adding at the end the fol-  
2 lowing: “A group health plan may not re-  
3 duce its coverage of the costs of adult vac-  
4 cines (as defined under section  
5 317A(a)(5)(B) of the Public Health Serv-  
6 ice Act) below the coverage provided by the  
7 plan as of July 1, 2008.”.

8 (B) MONITORING BY IG.—The Inspector  
9 General of the Department of Labor shall sub-  
10 mit an annual report to the Congress on imple-  
11 mentation and enforcement of the requirement  
12 of section 609(d) of the Employee Retirement  
13 Income Security Act of 1974 (29 U.S.C.  
14 1169(d)), as amended by subparagraph (A),  
15 that a group health plan not reduce its coverage  
16 of the costs of adult vaccines below the coverage  
17 provided by the plan as of July 1, 2008.

18 (2) UNDER IRC.—

19 (A) IN GENERAL.—Section 4980B(f)(1) of  
20 the Internal Revenue Code of 1986 is amended  
21 by inserting after “1993,” the following: “the  
22 coverage of the costs of adult vaccines (as de-  
23 fined in section 317A(a)(5)(B) of the Public  
24 Health Service Act) is not reduced below the

1 coverage provided by the plan as of July 1,  
2 2008,”.

3 (B) MONITORING BY IG.—The Inspector  
4 General of the Department of the Treasury  
5 shall submit an annual report to the Congress  
6 on implementation and enforcement of the re-  
7 quirement of section 4980B(f)(1) of the Inter-  
8 nal Revenue Code of 1986, as amended by sub-  
9 paragraph (A), that a group health plan not re-  
10 duce its coverage of the costs of adult vaccines  
11 below the coverage provided by the plan as of  
12 July 1, 2008.

13 (3) UNDER PHSA.—

14 (A) IN GENERAL.—Section 13631(d) of  
15 the Omnibus Budget Reconciliation Act of 1993  
16 (Public Law 103–66; relating to title XXII of  
17 the Public Health Service Act) is amended—

18 (i) in the heading, by inserting “OR  
19 ADULT” after “PEDIATRIC”; and

20 (ii) in paragraph (1), by adding at the  
21 end the following: “Such requirement also  
22 includes, with respect to a group health  
23 plan for plan years beginning after the  
24 date of the enactment of this sentence, the  
25 requirement that the group health plan not

1           reduce its coverage of the costs of adult  
2           vaccines (as defined in section  
3           317A(a)(5)(B) of the Public Health Serv-  
4           ice Act) below the coverage provided by the  
5           plan as of July 1, 2008.”.

6           (B) MONITORING BY IG.—The Inspector  
7           General of the Department of Health and  
8           Human Services shall submit an annual report  
9           to the Congress on implementation and enforce-  
10          ment of the requirement of section 13631(d) of  
11          the Omnibus Budget Reconciliation Act of 1993  
12          (Public Law 103–66), as amended by subpara-  
13          graph (A), that a group health plan not reduce  
14          its coverage of the costs of adult vaccines below  
15          the coverage provided by the plan as of July 1,  
16          2008.

17          (4) EFFECTIVE DATE.—The amendments made  
18          by paragraphs (1)(A), (2)(A), and (3)(A) shall apply  
19          to group health plans for plan years beginning after  
20          the date of the enactment of this Act.

21 **SEC. 3. AMENDMENTS TO PROGRAM OF VACCINE-RELATED**  
22 **GRANTS TO STATES.**

23          Section 317 of the Public Health Service Act (42  
24          U.S.C. 247b) is amended—

1           (1) in subsection (j), by adding at the end the  
2 following:

3           “(3)(A) For grants described in subsection (l)  
4 (relating to immunizing individuals without charge),  
5 there are authorized to be appropriated  
6 \$500,000,000 for fiscal year 2009 and such sums as  
7 may be necessary for each subsequent fiscal year.

8           “(B) Of the amount appropriated pursuant to  
9 this paragraph for each of fiscal years 2009 and  
10 2010, the Secretary shall reserve not less than  
11 \$80,000,000 for the purpose of providing immuniza-  
12 tions for adults who have not, prior to fiscal year  
13 2009, been served by immunization programs car-  
14 ried out with grants made pursuant to this section”;  
15 and

16           (2) by adding at the end the following:

17           “(l)(1) In making grants under subsection (a), the  
18 Secretary may make grants for preventive health service  
19 programs to provide immunizations without charge.

20           “(2) Subject to paragraphs (3) through (5), grants  
21 made pursuant to this subsection shall be made in accord-  
22 ance with criteria of the Secretary issued under para-  
23 graphs (1) and (2) of subsection (j) for immunization pro-  
24 grams. The preceding sentence may not be construed as

1 terminating the authority of the Secretary to modify such  
2 criteria.

3 “(3) Grants made pursuant to this subsection may  
4 be expended to improve the ability of a State health au-  
5 thority, a political subdivision of a State, or another public  
6 entity to improve an immunization program, including  
7 through the following:

8 “(A) Conducting assessments to determine the  
9 number of adults in the area involved who need im-  
10 munizations and the barriers to providing immuniza-  
11 tions to such adults.

12 “(B) Developing and implementing strategies to  
13 increase the rate of immunizations in populations in  
14 which a significant number of individuals have not  
15 received immunizations with the federally rec-  
16 ommended vaccines (as defined in section 317A(d))  
17 for the populations.

18 “(C) Educating care givers, health care profes-  
19 sionals, and the public about the need to be immu-  
20 nized.

21 “(D) Consulting with health care providers with  
22 respect to ensuring proper and timely immunizations  
23 for their patients.

24 “(E) Investigating and responding to outbreaks  
25 of vaccine-preventable diseases.



1           “(F) Developing and modifying plans to re-  
2           spond to potential shortages in supplies of vaccines.

3           “(G) Preparing reports under paragraph (5)  
4           and any additional reports that are submitted to the  
5           Secretary pursuant to this paragraph.

6           “(4) A condition for the receipt of a grant by a State,  
7           a political subdivision of a State, or another public entity  
8           made pursuant to this paragraph for a fiscal year is that  
9           the State, political subdivision, or public entity have (or  
10          agree to develop, in the case of a grant for fiscal year  
11          2008) a State plan that—

12           “(A) ensures the distribution and administra-  
13           tion of vaccines in the event that the Secretary de-  
14           clares a shortage of approved vaccines as a public  
15           health emergency; and

16           “(B) includes plans for communication and co-  
17           ordination between—

18           “(i) State and local public health depart-  
19           ments;

20           “(ii) community health centers;

21           “(iii) hospitals;

22           “(iv) private physicians licensed within the  
23           State; and

24           “(v) to the extent practicable, vaccine man-  
25           ufacturers and suppliers.

1       “(5) A condition for the receipt of a grant made pur-  
 2       suant to this paragraph for a fiscal year is that the appli-  
 3       cant involved agree to submit to the Secretary a report  
 4       that specifies for such year the quantity of each type of  
 5       vaccine purchased with the grant and the per-dose cost  
 6       of the vaccine.”.

7       **SEC. 4. PROHIBITION ON MEDICAID COST-SHARING FOR**  
 8                               **VACCINES RECOMMENDED BY ADVISORY**  
 9                               **COMMITTEE ON IMMUNIZATION PRACTICES.**

10       (a) IN GENERAL.—Section 1916 of the Social Secu-  
 11       rity Act (42 U.S.C. 1396o) is amended—

12               (1) in subsection (a), by striking “and (i)” and  
 13       inserting “, (i), and (j)”; and

14               (2) by adding at the end the following new sub-  
 15       section:

16       “(j) The State plan shall require that no provider  
 17       participating under the State plan may impose a copay-  
 18       ment, cost sharing charge, or similar charge for admin-  
 19       istering to an adult individual who is eligible for medical  
 20       assistance under such plan a federally recommended vac-  
 21       cine (as defined in section 317A(d) of the Public Health  
 22       Service Act).”.

23       (b) CONFORMING AMENDMENT.—Section  
 24       1916A(a)(1) of such Act (42 U.S.C. 1396o–1(a)(1)) is

1 amended by inserting “(other than subsection (j))” after  
 2 “Notwithstanding sections 1916”.

3 (c) EFFECTIVE DATE.—The amendment made by  
 4 subsection (a) shall take effect on the date of the enact-  
 5 ment of this Act.

6 **SEC. 5. MEDICARE AND MEDICAID PROGRAMS; STANDARDS**  
 7 **TO MEASURE USAGE AND COVERAGE OF**  
 8 **ADULT IMMUNIZATIONS.**

9 (a) IN GENERAL.—The Secretary of Health and  
 10 Human Services, acting through the Administrator of the  
 11 Centers for Medicare & Medicaid Services, shall establish  
 12 standards for the measurement of use by beneficiaries  
 13 under the Medicare and Medicaid programs of routinely  
 14 recommended adult immunizations.

15 (b) STUDY FOR USE OF STANDARDS AS A QUALITY  
 16 MEASURE.—The Secretary of Health and Human Serv-  
 17 ices, acting through the Administrator of the Centers for  
 18 Medicare & Medicaid Services, shall conduct a study to  
 19 determine the feasibility and advisability of including adult  
 20 immunization by Medicare and Medicaid beneficiaries, as  
 21 a performance measure under quality initiatives conducted  
 22 by the Secretary under the Medicare and Medicaid pro-  
 23 grams.

24 (c) MEASUREMENT OF USAGE BY HEALTH CARE  
 25 WORKERS.—The Secretary of Health and Human Serv-

ices, acting through the Administrator of the Centers for Medicare & Medicaid Services, shall establish standards for the measurement of use by health care workers, as defined by the Secretary for purposes of this section, working in a provider of services (as defined in section 1861(u) of the Social Security Act (42 U.S.C. 1395x(u)) of adult immunizations for influenza.

(d) ASSESSMENT OF BEST PRACTICES TO IMPROVE COVERAGE OF ADULT IMMUNIZATIONS.—The Secretary of Health and Human Services, acting through the Agency for Healthcare Research and Quality, shall conduct a study of the best practices of health insurers and managed care organizations to encourage the use of adult immunizations by enrollees of such insurers and organizations.

**SEC. 6. STUDY ON ADULT IMMUNIZATION FOR INFLUENZA FOR HEALTH CARE WORKERS AS A QUALITY INDICATOR FOR PURPOSES OF ACCREDITATION.**

(a) STUDY.—The Secretary of Health and Human Services shall conduct a study to determine the feasibility and advisability of including as a requirement of accreditation of a provider of services (as defined in section 1861(u) of the Social Security Act (42 U.S.C. 1395x(u)) compliance with recommended adult immunizations, including influenza, for all health care workers employed by the pro-

1 vider of services. Any such requirement should include a  
 2 provision for informed refusal by the health care worker  
 3 of the immunization and appropriate documentation of  
 4 usage and refusal of such immunizations.

5 (b) REPORT.—Not later than one year after the date  
 6 of the enactment of this Act, the Secretary shall submit  
 7 to Congress a report on the study conducted under sub-  
 8 section (a), and shall include in that report a description  
 9 of the difficulties of implementing such a requirement as  
 10 well as recommendations for the resolution of those dif-  
 11 ficulties.

12 **SEC. 7. FEHBP COVERAGE OF QUALIFIED IMMUNIZATION**  
 13 **SERVICES.**

14 (a) IN GENERAL.—Section 8902 of title 5, United  
 15 States Code, is amended by adding at the end the fol-  
 16 lowing:

17 “(p)(1) A contract may not be made or a plan ap-  
 18 proved which does not—

19 “(A) offer qualified immunization services to el-  
 20 igible enrollees, and

21 “(B) provide for the waiver of any deductible  
 22 that might otherwise apply with respect to any such  
 23 services provided to any such enrollee

24 “(2) For purposes of this subsection—

1           “(A) the term ‘qualified immunization services’  
2       means the provision and administration of all feder-  
3       ally recommended vaccines (as defined in section  
4       317A(d) of the Public Health Service Act); and

5           “(B) the term ‘eligible enrollee’, as used with  
6       respect to a health benefits plan, means an indi-  
7       vidual enrolled in such plan under this chapter who  
8       is 18 years of age or older.”.

9       (b) EFFECTIVE DATE.—The amendment made by  
10   this section shall apply to services provided under any con-  
11   tract entered into or renewed for any contract year begin-  
12   ning later than 9 months after the date of the enactment  
13   of this Act.

○